IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NORTHEASTERN DIVISION

ANDREW SCOTT RODRIGUEZ,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Civil Action No. 2:08-cv-124**
	)	**Judge Trauger**
STRYKER CORPORATION, *et al.*	)	**Magistrate Bryant**
	)	**JURY DEMAND**
Defendants.	)	
	)	

MEMORANDUM IN SUPPORT OF STRYKER'S MOTION TO EXCLUDE REBUTTAL TESTIMONY OF LONNIE E. PAULOS, M.D., PURSUANT TO *DAUBERT* AND FRE 702

Defendants, Stryker Corporation and Stryker Sales Corporation (collectively "Stryker Defendants"), by and through counsel, submit this memorandum in support of their motion to exclude the rebuttal testimony of Lonnie E. Paulos, M.D.[1]

As the evidentiary gatekeeper, this court assesses proposed opinion testimony using the three-part test of FRE 702 and the admissibility criteria detailed by the U.S. Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals* and its progeny. Under those standards, Dr. Paulos' proposed opinions are inadmissible because they are not based on *any* identified facts or data or on *any* identified scientific methodology. Dr. Paulos' opinions are classic *ipse dixit*, and this court should exclude them.

OPINIONS TO BE EXCLUDED

As required by Federal Rule of Civil Procedure 26(a)(2)(B) and relevant case law (*see* Discussion, *infra*), Dr. Paulos' proposed opinion testimony and the foundations for his opinions are set forth in his eight-page report dated October 12, 2010. (Paulos Rpt., attached as Ex. A.)

[1] Dr. Paulos' proposed testimony is also improper rebuttal and unnecessarily duplicative. *See* Stryker's Mot. to Excl. Rebuttal Experts, filed concurrently with this motion.

Dr. Paulos' report focuses primarily on his opinion regarding general causation, specifically that "there is virtual unanimity of agreement that the use of intra-articular pain pumps can be a cause of chondrolysis and subsequent destruction of the shoulder joint." (*Id.* at 4.) In support of this opinion, Dr. Paulos relies on his "observations" of "incidences of chondrolysis following use of pain pumps" in one of his patients and in other patients that he "heard about." (*Id*. at 3-5.) Dr. Paulos does not provide any facts or data regarding any of these "incidences of chondrolysis." (*Id.*) As additional support, Dr. Paulos points to "numerous articles" and a "number of basic science experiments," none of which he identifies in even the most basic fashion. (*Id*.)

Dr. Paulos also opines – again without pointing to *any* facts or data – that the Stryker Defendants failed to properly label and market the pain pumps because neither the labels nor the sales representative told "surgeons that the FDA had denied clearance for use in the synovial cavity." (*Id*. at 7.) Dr. Paulos does not have any experience or qualifications regarding product labeling or warnings. (*Id*. at 1-2.)

DISCUSSION

Rule 702 of the Federal Rules of Evidence requires the proponent of expert testimony to show that: "(1) the testimony is based upon sufficient facts and data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." Fed. R. Evid. 702; *Daubert* v. *Merrell Dow Pharm., Inc.,* 509 U.S. 579, 589 (1993). The offering party bears the burden of establishing admissibility by a preponderance of the evidence. *See* Fed. R. Evid. 104(a); *Daubert*, 509 U.S. at 592 n.10.

The proposed expert's Rule 26 report itself must satisfy the admissibility criteria. *Tompkin v. Phillip Morris*, 362 F.3d 882, 895 (6th Cir. 2004); *Brainard v. American Skandia Life Assur. Corp*., 432 F.3d 655 (6th Cir. 2005). Thus, the report must contain more than

conclusory assertions about ultimate issues. *Brainard*, 432 F.3d at 663, 664 (citing *Viterbo v. Dow Chem. Co.* 826 F.2d 420 , 422 (5th Cir. 1987), quoting *Hayes v. Douglas Dynamics*, 8 F.3d 88, 92 (1st Cir. 1993) ("An expert who supplies nothing but a bottom line supplies nothing of value to the judicial process.").

I. Dr. Paulos' proposed testimony is not based on *any* "facts and data."

Conclusions alone are simply not good enough to permit the admission of "expert" testimony, no matter how well qualified the expert. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("*ipse dixit* of the expert" is not sufficient to allow admission of opinion); *Tamraz v. Lincoln Elec., Co.,* 2010 U.S. App. LEXIS 18732 at *15 (6th Cir. Sept. 8, 2010). An expert must rely on facts and data – and scientific testing – or his opinions are inadmissible. Fed. R. Evid. 702.

As the Sixth Circuit recently explained, courts must apply the *Daubert* principles with particular care in assessing proposed causation testimony from physicians. *Tamraz*, 2010 U.S. App. LEXIS 18732 at *21. This is because "most treating physicians have more training in and experience with diagnosis than etiology." *Id*. at *20. Thus:

> When physicians think about etiology in a clinical setting … they may think about it in a different way from the way judges and juries think about it in a courtroom. Getting the diagnosis right matters greatly to a treating physician, as a bungled diagnosis can lead to unnecessary procedures at best and death at worst. But with etiology, the same physician may often follow a precautionary principle: If a particular factor *might* cause a disease, and the factor is readily avoidable, why not advise the patient to avoid it? … This low threshold for making a decision serves well in the clinic but not in the courtroom, where decision requires not just an educated hunch but at least a preponderance of the evidence.

Id. at *20-*21.

Dr. Paulos does not rely on any facts and data for his opinions, other than vague

assertions about patients with chondrolysis. He does not identify any specific facts or data he gathered to reach his opinions, nor does he identify facts or data gathered by others. (Paulos Rpt. at 3-5, attached as Ex. A.) Expert opinions must be based on a reliable foundation, and Dr. Paulos' opinions are not.

II. Dr. Paulos' opinions are not based on "reliable principles and methods."

Rule 702's second and third requirements mandate that experts employ reliable principles and methods and reliably apply those principles and methods to the matter before them. Fed. R. Evid. 702. An expert must not only employ reliable principles and methods, he must explain them in his report. *Brainard*, 432 F.3d at 664 (affirming exclusion of expert whose report contained no "meaningful analysis and reasoning"); *Minix v. Canarecci*, 597 F.3d 824, 835 (7th Cir. 2010) (affirming exclusion of expert testimony in light of expert's "failure to explain his methodology"). If an expert does not explain the methodology used to reach his opinions, there is no way for the court to assess whether the methodology is reliable.

Dr. Paulos does not explain – and apparently does not employ – *any* methodology, much less a reliable methodology. He simply says that a causal relationship between pain pumps and chondrolysis exists, and asks this court – and ultimately proposes to ask a jury – to believe that it is so.

In contrast, the "reliable principles and methods" of Rule 702's second prong are generally those of empirical science. "The first and most significant *Daubert* factor is whether the scientific theory has been subjected to the scientific method." *Bradley v. Brown*, 42 F.3d 434, 438 (7th Cir. 1994); *see Miller v. Mandrin Homes, Ltd.*, 305 Fed. Appx. 976, 979 (4th Cir. 2009).

Scientific inquiry identifies all reasonable possibilities for an observed phenomenon and

systematically tests the validity of each one. The process is known as "falsification." *See* David Goodstein, *How Science Works*, in *Reference Manual on Scientific Evidence*, 67, 70 (2nd ed. 2000) (citing Karl R. Popper, *The Logic of Scientific Discovery* (1959).) What usually distinguishes theory from admissible opinion testimony is whether a proposed theory can be and has been tested. *Daubert,* 509 U.S. at 593.

With regard to medical causation, proposed expert testimony must systematically rule in potential causes and rule out rejected causes. *Tamraz*, 2010 U.S. App. LEXIS 18732 at *23-*24. Dr. Paulos does not apply any methodology – much less a valid methodology – to do either rule in or rule out potential causes. Dr. Paulos' report nowhere describes or identifies the principles or methodologies he employed, other than stating that he observed one patient of his own and "heard about" other patients who allegedly experienced chondrolysis following the use of a pain pump. (Paulos Rpt. at 3-4, attached as Ex. A.)

Thus, Dr. Paulos' opinions should be excluded.

III. Dr. Paulos is not qualified to offer opinions regarding product labeling.

To offer opinion testimony, a proposed expert must be qualified in the relevant field. *Ervin v. Johnson & Johnson, Inc.,* 492 F.3d 901, 904 (7th Cir. 2007). To testify regarding product warnings and labeling, an expert must be sufficiently experienced in human factors, and specifically product labeling or warning design. *Lemmermann v. Blue Cross Blue Shield*, 2010 U.S. Dist. LEXIS 50477 at *24-*25 (E.D. Wisc. May 18, 2010). Merely being a user of a particular product is not sufficient. *See id.*

Dr. Paulos does not have any experience in product labeling, warning design, or human factors. (*See* Paulos Rpt. at 1-2, attached as Ex. A.) Thus, his opinions regarding the appropriateness of the labeling and warnings for Stryker's pain pumps should be excluded.

IV. Dr. Paulos' proposed testimony regarding his personal interaction and communications with the Stryker Defendants is irrelevant.

Under Rule 702, the trial court must assess not just scientific validity, but also "fit"—whether the proposed testimony is applicable to the case. *See Daubert,* 509 U.S. at 589. Dr. Paulos' report contains details regarding his personal interactions and communications with Stryker. For instance, Dr. Paulos states that in 2005 he notified Stryker of his belief that there was a potential association between pain pumps and chondrolysis and that he made recommendations regarding pain pump labeling. (Paulps Rpt. at 3-4, attached as Ex. A.) He also states that, at some unidentified time, Stryker representatives marketed pain pumps to him and "to others" for use "directly into the intra-articular spaces of the knee and shoulder." (Paulos Rpt. at 6, attached as Ex. A.)

Dr. Paulos's personal interactions with Stryker have nothing to do with either general causation or labeling. Whether pain pumps can cause chondrolysis is a scientific inquiry independent of any communications between Stryker and any physician. And the same is true of the adequacy of the product labeling.

Moreover, any alleged recommendations or warnings that Dr. Paulos made to Stryker *in 2005* are irrelevant because they occurred *after* the date of plaintiff's surgery, November 15, 2004. (Kuhn Dep. at 31-32, attached as Ex. B.) Dr. Paulos does not indicate when Stryker representatives marketed pain pumps to him, and unidentified "others," so those statements are also irrelevant.

In addition, the physician who placed plaintiff's pain pump, Dr. Kuhn, testified that he learned how to use pain pumps independent of *any* communications with Stryker representatives and that he did not remember the substance of any conversations with any Stryker representatives. (Depo. of Dr. Kuhn at 17-18, excerpt attached as Ex. B.) Thus, whatever

Stryker representatives may have said to Dr. Paulos is completely irrelevant because it had no bearing on Dr. Kuhn's decisions with regard to plaintiff. Thus, the court should exclude Dr. Paulos' proposed testimony regarding his personal interactions with Stryker.

WHEREFORE, defendants Stryker Corporation and Stryker Sales Corporation respectfully request that the Court exclude the proposed testimony of Dr. Lonnie Paulos.

Respectfully submitted,

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